DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 25, 2015

Covidien
Debbie Peacock
Regulatory Product Manager
60 Middletown Ave.
North Haven, CT 06473

Re: K143088
Trade/Device Name: Gastrisail Gastric Positioning System
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: KNT
Dated: January 9, 2015
Received: January 12, 2015

Dear Debbie Peacock,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K143088

Device Name
GastriSail™ Gastric Positioning System

Indications for Use *(Describe)*

The GastriSail™ Gastric Positioning System is indicated for use in gastric and bariatric surgical procedures for the application of suction, decompression and to radially expand the stomach, to drain gastric fluids, to test for leaks, to provide visible and tactile delineation of the lesser curvature of the stomach and to serve as a sizing guide for gastric and bariatric procedures, such as sleeve gastrectomy.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Traditional 510(k) Summary

SUBMITTER:	Covidien llc 60 Middletown Avenue North Haven, CT 06473 USA
CONTACT PERSON:	Debra Peacock Regulatory Affairs Product Manager Covidien llc Phone: (203) 492-6935 Fax: (203) 492-5029 e-mail: debra.peacock@covidien.com
DATE PREPARED:	10/27/2014
PRODUCT CODE:	KNT
REGULATION NUMBER:	21CRF 876.5980
REVIEW PANEL:	Gastroenterology/Urology
TRADE/PROPRIETARY NAME:	GastriSail™ Gastric Positioning System
COMMON/USUAL NAME:	Gastric Positioning System
CLASSIFICATION NAME:	Tubes, Gastrointestinal (and Accessories)
PREDICATE DEVICES:	1). Realize™ Gastric Calibration Tube (K071764). Mfg by Ethicon 2). ViSiGi3D™ Sleeve Gastrectomy Calibration System with Bulb (K130483). Mfg by Boehringer Laboratories
DEVICE DESCRIPTION:	The GastriSail™ Gastric Positioning System is a 36FR flexible, non-sterile, single-use, dual lumen gastric tube designed to be inserted into the esophagus by an anesthesiologist for use in gastric and bariatric surgical procedures, such as sleeve gastrectomy. The GastriSail™ Gastric Positioning System consists of a dual lumen flexible tube. One lumen houses the Sail feature and integrated LED guidelights, and the other lumen has rows of distal holes which, when connected to suction provides vacuum to the stomach for evacuation of stomach contents and suction fixation along the lesser curvature of the stomach. This lumen is also used to perform leak testing at the end of the procedure.

INTENDED USE

The GastriSail™ Gastric Positioning System is indicated for use in gastric and bariatric surgical procedures for the application of suction, decompression and to radially expand the stomach, to drain gastric fluids, to test for leaks, to provide visible and tactile delineation of the lesser curvature of the stomach and to serve as a sizing guide for gastric and bariatric procedures, such as sleeve gastrectomy.

CHARACTERISTICS	**Proposed GastriSail™ Gastric Positioning System**	**Predicate ViSiGi 3D (K130483)**	**Predicate Realize™Gastric Calibration Tube (K071764)**
IFU	The GastriSail™ Gastric Positioning System is indicated for use in gastric and bariatric surgical procedures for the application of suction, decompression and to radially expand the stomach, to drain gastric fluids, to test for leaks, to provide visible and tactile delineation of the lesser curvature of the stomach and to serve as a sizing guide for gastric and bariatric procedures, such as sleeve gastrectomy.	The ViSiGi 3D™ is indicated for use in gastric and bariatric surgical procedures for the application of suction, stomach decompression, drainage of gastric fluids, irrigation and to serve as a sizing guide.	The Ethicon Endo-Surgery Gastric Calibration Tube is indicated for use in gastric and bariatric surgical procedures to provide visible and tactile delineation of the antrum of the stomach along with the ability to decompress the stomach, drain and remove gastric fluid, and size a gastric pouch.
Length of tube	132 cm (total)	107 cm	74.5 cm
Tubing	Multi lumen with rounded, closed distal end	Single lumen with rounded, closed distal end	Single lumen with rounded, closed distal end
Size	36 Fr	36 and 40 Fr	38 Fr
Sterility	Clean, Non Sterile, single-patient use	Same	Same
Suction fixation	Yes	Yes	Yes
Decompression capability	Yes	Yes	Yes
Sail feature	Yes	No	No
LED Guide lights	Yes	No	No
Disposable	Yes	Yes partly	Yes

MATERIALS:	Materials have been tested for Biocompatibility in accordance with ISO 10993-1:2009
PERFORMANCE DATA:	Design verification studies and Performance studies were conducted as summarized below: GastriSail™Non-clinical Testing: • Dimensional analysis • Tensile testing of adhered bonds • Battery functional testing • Vacuum relief testing • Suction tubing adapter test Comparative testing to the predicate device, Realize™ Gastric Calibration Tube • Decompression of the stomach: • Suction fixation and evacuation of stomach contents • Sizing of a Gastric Sleeve In-vivo Evaluation of esophageal insertion test in porcine Electrical Safety Testing: • IEC 60601-1: Ed3 • IEC 60601-1-2: Ed 4
CONCLUSION:	It has been demonstrated that the proposed GastriSail™ Gastric Positioning System is substantially equivalent to the legally-marketed Ethicon Realize™ Gastric Calibration Tube (K071764), and to the Boehringer ViSiGi3D™ Sleeve Gastrectomy Calibration System with Bulb (K130483).